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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/050,655	01/16/2002	Damian J. Gallina	01-496-A	7537

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EXAMINER	
WINSTON, RANDALL O	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 11/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	10/050,655	GALLINA, DAMIAN J.	
	Examiner	Art Unit	
	Randall Winston	1654	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 16 September 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☒ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *see continuation sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: 25-32.

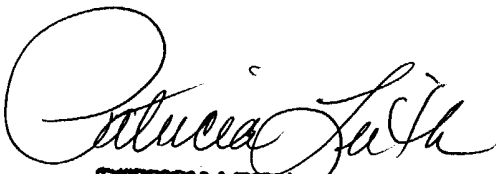
   Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☒ Other: *See Continuation Sheet*

Continuation of 10. Other: Applicants' arguments have been fully considered. Although applicants have made the new argument that the claims are directed to a pharmaceutical composition comprising HIV infected cells that have been treated with hyaluronidase and not to a method, therefore, the inquiry is whether the specification enables the claimed composition. However, claims 25-32 still stand rejected under both the New Matter Rejection and the Enablement Rejection under 35 USC 112, first paragraph, as for the same reasons set forth in examiner's final rejection on 07/14/2004. Applicants' have not overcome the New Matter Rejection because the support for the limitation on page 9 for the "human cell line" does not adequately describe and/or not representive by a "human peripheral blood mononuclear cells" explained on page 9. Also, Applicants have not overcome the 35 USC 112, first paragraph, rejection because one of ordinary skill in the art would not be able to practice Applicants' in vitro assays of HIV infected cells that have been treated with hyaluronidase in vitro for the intended purpose of the in vivo activation of immune system cells against HIV. Thus, since applicants' in vitro experimental data presented is clearly not drawn to the in vivo activation of immune system cells against HIV, applicants are only enabled for a pharmaceutical composition for in vitro activation of immune system cells against HIV comprising HIV infected cells that have been treated with hyaluronidase in vitro because the specification does not enable any person in the art to create a pharmacetical composition for in vivo activation of immune system cells against HIV comprising HIV infected cells that have been treated with hyaluronidase in vitro. Also, although applicants' argue that the reference was published in 1983, thus, the reference should not be considered state of the art, examiner's position is that since the pharmaceutical composition was created to be effective against HIV, the state of the art for the treatment of HIV still reflects that there is no direct correlation between applicants' in vitro assays against HIV as indicative of in vivo activity against HIV. Therefore, based on the teachings of unpredictability regarding in vivo therapy against HIV, persons skilled in the art would not associate in vitro results against HIV with in vivo therapeutic efficacy against HIV.



PATRICIA LEITH
PRIMARY EXAMINER